

Connecting Technology Businesses Globally

The **First Phase** of an operational startup

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Marvin Ng set up DN Venture Partners (Singapore/Germany) in early 2000 to assist life sciences firms with their business development activities in Asia and Europe. He has helped life sciences firms ranging from startups to MNCs, including top pharmaceutical and medical technology companies that are expanding their business and R&D activities internationally.

The new Singapore Medical Engineering and Technology (MET) Guide has been specially created to offer useful industry information to Medical Technology (Med Tech) companies in the fledging Medical Technology industry, in particular those that are planning new operations in Singapore.

For the purpose of this guide, we have chosen to loosely define a Med Tech company as one that applies or develops technology, device or procedure for the diagnosis and treatment of diseases in an attempt to promote or restore wellness and improve quality of life.

Since the successful launch of our Singapore Biotech Startup Guide in 2003 (subsequently renamed Singapore Biotech Guide and available online at www.biotechsingapore.com), we have found that such startup information is valuable to companies involved or interested in the local biotech industry. New inbound foreign companies have found the business startup information to be especially useful during their initial business formation and budget planning phase. On the other hand, existing companies have found the up-to-date overview of the various grant schemes and operational license requirements to be helpful as they continue to maximize their operational efficiencies.

In this first edition of the Singapore MET Guide, we intend to apply our successful formula for the Singapore Biotech Guide but focus the content on information that will be relevant to the Med Tech community at large. However, given the wide range of technologies, applications and activities that may be classified under Medical Technology, we quickly realized that the extent of information coverage may never be all-inclusive. We have thus chosen to highlight the essentials here and hope that you will offer feedback on additional contents that you will like to see in future editions. We will be happy to receive your feedbacks via email at medguide@dn-venture.com.

Happy Reading!

UNCOVER BIOTECH BUSINESS OPPORTUNITIES IN ASIA

We are a specialist consulting firm committed to helping companies succeed in the biotech industry in Asia. From our offices in Singapore and Germany, we have supported clients in critical business areas including:

- Business development
- Business and market planning
- Fund raising
- Government grant application
- Market research and intelligence



Getting started

Singapore and Its Law

Written laws in Singapore take the form of Statutes made by the Singapore Parliament and official administrative bodies. In addition, subsidiary Legislations that accompany the Singapore Acts comprise rules and regulations that regulate the manner in which the Act is to be administered.

The entire Singapore Statutes is available online at the Singapore Attorney-General's Chambers website (<http://statutes.agc.gov.sg>) while the Subsidiary Legislation is available via monthly online subscription at the LawNet website (www.lawnet.com.sg). Printed copies of the documents may also be purchased online at <http://www.snpcorp.com/webshop/>.

These documents lay the rules on how businesses and other matters should be conducted in Singapore. More importantly, they spell out the procedures and requirements for the various licenses and permit applications. Some of the more common ones are described below and reference made to the relevant Statutes and Subsidiary Legislation. Companies are advised to check with the various government ministries and agencies on other licenses and permits that may also be relevant to them.

Company Registration

Prior to performing business activities in Singapore, one will need to register his business or company with the Accounting and Corporate Regulatory Authority (ACRA) (www.acra.gov.sg). Registration may be performed online at www.bizfile.gov.sg via SingPass authentication. SingPass (www.singpass.gov.sg) is a set of authentication ID and password issued to all Singapore Citizens, permanent residents and valid employment and dependent pass holders.

Alternatively, foreigners without SingPass may wish to approach a professional firm (lawyers, accountants or chartered secretaries) or a service bureau for assistance with the online application submission.

Businesses may be registered, under the Business Registration Act, as sole proprietorship or as partnership firms or incorporated as companies under the Companies Act. A Business firm is exposed to unlimited liability and either the sole proprietor himself or all the partners in the firm are liable for all the debts of the businesses. On the other hand, a Company adopts a separate legal personality and its members cannot be sued in respect of liabilities incurred by the company nor be held liable for the company's debts. However, there are provisions in the Companies Act to curb abuse. A third type of corporate entity, known as Limited Liability Partnership, enables business owners to operate as a partnership while being granted limited liability.

Most Med Tech companies will probably start off by incorporating itself as a private company limited by shares (or Private Limited), with less than 50 shareholders or members and with liability of each of its members limited to the amount paid on the shares held.

On the other hand, a foreign company expanding into Singapore may choose to either incorporate a Singapore subsidiary or register a Singapore branch. The former is a new legal entity incorporated under the Companies Act while the latter is treated as an extension of the company incorporated elsewhere and merely registered in Singapore. All foreign companies are regulated by the relevant sections in the Companies Act and by the law of the place of its incorporation.

Operational License and Registration with Government Agencies

Depending on the nature of your operation, there are several operating permits and licenses that one will also need to get hold of prior to initiation of business. Some of the more common ones are described below:

GENERAL REQUIREMENTS FOR ALL TYPES OF OPERATIONS

Factory Registration and Workplace Safety & Health Regulations

It is common for a Med Tech setup to be classified as a Factory under the Workplace Safety and Health Act (WSHA) (accessible online at <http://statutes.agc.gov.sg>).

Depending on the type of factory operation, either a notification or registration with the Ministry of Manpower (MOM; www.mom.gov.sg) may be required. On the other hand, some of you may find the definition of a factory to only partially describe the type of operation that you are planning. We will thus recommend that you seek clarification with the Occupational Safety and Health Division of MOM if you are in doubt.

Furthermore, the WSHA and its Regulations set the legal framework for occupational safety and health (OSH) management at workplaces in Singapore. The First Schedule of the WSHA lists the types of workplaces that the various regulations will apply. Importantly, the WSH (Risk Management) Regulations 2006 requires all scheduled workplaces to conduct a properly documented safety and health risk assessment prior to undertaking any work within the premise. We will like to stress the importance of risk assessment as an essential undertaking during the operations planning stage.

Industrial Premise Siting

The impact of an industrial project on the environment has to be assessed by the National Environment Agency (NEA) (www.nea.gov.sg) prior to construction through filing a Form IA application. The assessment includes impact on water, air, land and noise pollutions as well as hazardous substance and toxic waste controls. NEA published a code of practice on environmental pollution control to provide guidelines on the various emission limits requirements.

Furthermore, depending on the trade effluent to be discharged, various discharge licenses and written approvals may be needed prior to construction.

Tradenet - Import, Export and Transshipment

An import/export permit is required for the import/export of all goods into/out of Singapore. In Singapore, this documentation is managed via a nationwide electronic system known as Tradenet (www.tradexchange.gov.sg). Permit applications may be made electronically and approval granted via electronic messages. All traders (importer and exporter) are identified via a Central Registration (CR) number which may be applied for online at www.licences.business.gov.sg.

Employer Registration for Central Provident Fund Contribution

More information on the Central Provident Fund (CPF) may be found under the Human Resource: Staffing Matters section below. To make the first contribution, new employer is required to submit a duly completed Form CPF/1 along with a cheque for the contribution amount to CPF Board (www.cpf.gov.sg). A welcome package and the new employer reference number will subsequently be sent once the payment has been processed.

GST Registration

Companies and businesses with or reasonably expecting an annual taxable turnover exceeding S\$1 million are required to register for Goods and Services Tax (GST). GST is a consumption tax that is levied on all imported goods as well as most goods and services in Singapore. After registration, companies and businesses must charge and account for GST in their sales but may also claim for GST incurred on goods and services purchased for the business or as part of the business operation. More information on the GST may be found under the Taxes section below.

FOR OPERATIONS WITH CHEMICAL USAGE

Import, Sale, Storage, Use and Disposal of Hazardous Substances

The National Environment Agency (NEA) is also the government agency responsible for granting licenses and permits for the import, use, storage and transportation of hazardous substances as defined in the Environmental Pollution Control Act and Regulations. All applications may be made online at the NEA's website.

Hazardous Substances License – required for the import, sale or export of Hazardous Substances controlled under the Environmental Pollution Control Act.

Hazardous Substances Permit – required for the local purchase, storage and/or use of hazardous substances controlled under the Environmental Pollution Control (Hazardous Substances) Regulations.

Transport approval – required for the transport of hazardous substance in quantities exceeding those specified in the Environmental Pollution Control (Hazardous Substances) Regulations.

Furthermore, toxic industrial and biohazardous wastes are to be collected by NEA licensed collectors for off-site treatment and disposal. The generation and transportation of such wastes are also tracked online through the e-Tracking system. An updated list of these collectors is available at the NEA's website.

Import, Storage and Transport of Flammable Materials

Under the Fire Safety (Petroleum and Flammable Materials) Regulations 2005, a license from the Licensing & Enforcement Branch, Fire Safety & Shelter Department (FSSD) of the Singapore Civil Defence Force (SCDF) is required for the import, storage and transportation of petroleum and flammable materials gazetted in the regulation. Additional information may be found at www.scdf.gov.sg.

Furthermore, SCDF published a set of technical guidelines and fire safety requirements for premises handling chemicals.

The guidelines are downloadable from the SCDF website. SCDF also follows the Singapore Standard SS532:2007 as well as the US National Fire Protection Association (NFPA) Standards NFPA 45 and NFPA 55 when regulating flammable materials storage, use and handling.

Import License for poisons and controlled drugs

A Form A Poisons License is relevant and may be obtained for companies who intend to import, store and/or sell any of the scheduled poisons controlled under the Poisons Act, Chapter 234 and its Subsidiary Legislation. Additionally, as a requirement under the Misuse of Drugs Act, a license is required for possession, supply, import and manufacture of the scheduled controlled drugs.

Both licenses may be obtained from the Centre for Drug Administration (CDA), Health Sciences Authority (HSA) (www.hsa.gov.sg).

National Authority (Chemical Weapons Convention) NA(CWC) License

A NA(CWC) license is required for the production, processing, consumption, import/export and/or local sale/distribution of chemicals controlled under the CWC. Details on the scheduled chemicals and the application forms are available at www.customs.gov.sg/nacwc.

License to possess & store Explosive Precursors

Under the revised Arms and Explosives Act, a license from the Singapore Police Force is required to import, possess, deal in, manufacture and/or store a series of identified explosive precursors, many of which are oxidizing agents commonly used for lab chemistry and industrial applications. Protective security measures as well as threat and risk assessments are to be in place prior to license issuance. Applications may be filed online at www.spf.gov.sg.



OTHER REQUIREMENTS

Imports of Pathogens

The Biological Agents and Toxins Act 2006 (BATA) regulates the possession, usage, import, transfer and transportation of scheduled biological agents and toxin in Singapore. Stringent requirements for facility, work procedures and biosafety management systems were also stipulated in the Act. Permits for the import, possession and production of these biological agents and toxins were also required prior to initiation of the said works. More information, including a list of regulated agents and toxins, is available at the Ministry of Health's biosafety website (www.biosafety.moh.gov.sg).

In addition, import of clinical and pathological specimens must comply with the requirements laid down in the Agri-food and Veterinary Authority (AVA)'s Veterinary Regulations For The Importation of Products Of Animals and Birds (1/1) – Clinical / Pathological Specimens and any subsequent amendments. Prior approval from AVA is also needed for all imports of plants and plant products as well as veterinary biologics and microorganisms into Singapore. More information is available at AVA's website (www.ava.gov.sg).

License Related to Possession of Radioactive Materials

The Centre for Radiation Protection and Nuclear Science (CRPNS) under the National Environmental Agency (NEA) regulates the use of radioactive materials and irradiating apparatus in Singapore.

Guidelines are published by the agency on the possession and use of ionizing radiations, which include emissions of alpha and beta particles (i.e. most radioisotopes frequently used in a molecular biology or chemistry lab) as well as gamma rays and X-rays.

Under the Radiation Protection Act, a license is needed for the import, export, sale, possession and use of radioactive materials and apparatus. In addition, personal radiation monitoring is a requirement for all personnel handling such materials and apparatus. Proper storage and accountability of the radioactive materials in one's possession are also imperative. Few of the more common licenses are the L4, L6 and R1 licenses, which are applicable to companies that wish to possess radioactive materials for their own use as well as individuals that wish to be registered as radiation workers respectively. Further details along with the applications forms are available at the NEA's website (www.nea.gov.sg). Such premises are also subjected to routine inspection by officers from CRPNS.

Genetic Modification Advisory Committee (GMAC)

The GMAC oversees and provides advises on research and production of Genetically Modified Organisms (GMOs) in Singapore. The committee has since published guidelines pertaining to the control of release of agriculture-related GMOs as well as biosafety guidelines for research on GMOs. Specifically, the latter guidelines provide the

framework for assessment and notification of research on GMOs. Certain works involving genetic manipulation of organisms are to be approved by the institution's Institutional Biosafety Committee (IBC) and GMAC notified. More information on the guidelines may be found at www.gmac.gov.sg.

Use of Telecommunication Equipment

Some Med Tech products may involve the use of radiofrequency (RF) equipments. The Infocomm Development Authority of Singapore (IDA) is the agency that regulates all local use of telecommunication equipment. New telecommunication equipments are required to conform to the technical specification prescribed by the agency. More information may be found at www.ida.gov.sg.

ADMINISTRATION STARTUP

Taxes

Details of Singapore's tax regime can be found at the Inland Revenue Authority of Singapore's (IRAS) website at www.iras.gov.sg. The website provides comprehensive coverage on tax matters and is a valuable online resource. Some of the more relevant sections are summarized below:

Corporate Income Tax

Generally, companies are taxed on Singapore income and overseas income received in Singapore. The tax structure is straightforward with the current tax rate set at 18%. A partial tax exemption for the first \$300,000 of normal chargeable income (excluding Singapore franked dividends) is also given out from Year of Assessment 2008 onwards to help reduce the overall tax rates.

The current corporate tax structure is as follows:

Amount of chargeable income	Effective tax rate
First S\$10,000	4.5%
Next S\$290,000	9.0%
In excess of S\$300,000	18.0%

Furthermore, new start-up companies enjoy additional tax incentives:

Amount of chargeable income	Effective tax rate
First S\$100,000	0.0%
Next S\$200,000	9.0%
In excess of S\$300,000	18.0%

Personal Income Tax

Foreigners are considered Singapore tax residents if they spend 183 days or more in Singapore during the calendar year or if they have been working in Singapore for 3 consecutive years. Tax rates for residents depend on their total taxable income during the calendar year and range from 0% to 20%.

Non-residents are taxed only on income earned in Singapore. The applicable tax rate is the higher of 15% (with no personal reliefs) or the corresponding resident's rate (with personal reliefs). Additional information, including details on personal reliefs, may be found at the IRAS website.

Goods and Services Tax (GST)

The Goods and Services Tax (GST) is a domestic consumption tax that is levied on all goods and services supplied by GST-registered businesses.

The current GST rate is 7%. Businesses that expect their taxable turnover to exceed S\$1 million will need to register themselves as taxable persons. Taxable persons are eligible to recover GST paid on qualified business purchases (Input Tax) which may be significant for new companies during the startup phases. More information may be found at the IRAS website.

Withholding Tax

Payments to foreign companies and non-resident professionals for the following services rendered in Singapore are subject to withholding tax:

- i. interest, commission, fee or any other payment in connection with any loan or indebtedness
- ii. royalty or other payments for the use of or the right to use any movable property
- iii. fee for the use of or the right to use scientific, technical, industrial or commercial knowledge or information, or for the rendering of assistance or service in connection with the application or use of such knowledge or information
- iv. management fee
- v. rent or other payments for the use of any movable property
- vi. payment of any remuneration to any non-resident director, professionals or public entertainers

The applicable rate depends on the nature of the payments and can be up to 20% of gross income. The withheld amount is to be submitted to IRAS by the 15th of the month following the payment date.

Withholding tax can be significant to technology companies where international technology transfer and licensing deals are common. For example, a S\$5 million licensing fee to a foreign company will effectively become S\$5.5 million after including 10% of tax withheld.

HUMAN RESOURCE: STAFFING MATTERS

Contact Singapore is a resource centre with offices around the world that help those interested learn more about living and working in Singapore. The organization's website at www.contactsingapore.org.sg also provides key information on visas and employment matters. For details on Singapore's employment legislations, information can be obtained from the Ministry of Manpower's website at www.mom.gov.sg.

Recruitment Strategies

"To search or advertise?" That is a common question that companies ask themselves when recruiting. Executive search or headhunting strategies are probably more effective for senior positions. A list of international executive search firms may be found at the Contact Singapore website.

On the other hand, advertisement placements will allow companies to cast a wider net to get at a larger pool of applicants. Companies may choose between an online or a printed advertisement.

For online advertisements, the Contact Singapore website has a list of web links to online job search facilities in Asia where companies can post their job openings. For printed advertisements, companies can choose to advertise in local newspapers as well as international scientific journals (for scientific positions).

Singapore Press Holdings (SPH) is the leading newspaper publisher in Singapore; it publishes 13 newspapers including most read Straits Times. The latest advertisement rates may be obtained by contacting SPH via their website at www.sph.com.sg.

Employment Law and Guidelines

The main legislation governing employment in Singapore is the Employment Act which recently underwent a major revision. Part IV of the revised Act now states the minimum number of rest days, holidays and leaves, maximum hours of work, and other wage-related matters that are to be extended to non-workmen receiving less than \$2,000 basic monthly salary and workmen receiving no more than \$4,500 monthly salary.

Coverage under the Act is also now extended to the previously excluded group of confidential staff. Furthermore, managers and executives earning a basic monthly salary of \$2,500 and below are now protected against non-payment of salary and are granted access to MOM's Labour Court for salary claims. The recent amendment also re-defined part-time employees as those who work less than 35 hours a week (up from 30 hours a week). Additional medical leave benefits were also stipulated in the revised Act.

The Singapore Business Federation, Singapore National Employers Federation (SNEF) and National Trades Union

Congress issued a Code of Responsible Employment Practices in 2002 to promote good employment practices.

The code may be found online at http://www.sgemployers.com/public/industry/code_rep.jsp.

Compensation and Benefits

There is no "perfect" way to determine an appropriate salary for each employee. Some benchmarks may be obtained from the Ministry of Manpower's Report on Wages in Singapore (www.mom.gov.sg), the Contact Singapore website and the salary survey report published by the SNEF (www.sgemployers.com). However, accurate wage data for scientific positions in Singapore are still lacking as the medical technology industry here is still a young one.

Companies may find it useful to obtain comparable salary rates from salary reports and surveys from similar industries, both local and foreign, and adjust the latter rates accordingly to reflect the differences in costs of living, taxes, medical costs, benefits, etc.

It may also be useful to obtain copies of the Expatriate Living Costs in Singapore and The Investor's Guide to Singapore (both published by the Singapore International Chamber of Commerce) from major bookstores or online at www.sicc.com.sg.

CPF

The Central Provident Fund (CPF) is Singapore's version of a social security savings plan for retirement. Members may also use the fund for purposes like investment, healthcare, education and home ownership.

All employees who are Singapore citizens and Permanent Residents (PRs) contribute towards the CPF savings, with the latter contributing at a reduced rate during the first two year of becoming a PR. However, contributions are not required for expatriate employees on Employment Passes or Work Permits.

Employers currently contribute 14.5% of the employees' wages to the CPF for employees aged 50 years old and below. This rate is gradually reduced to 5% for those above 60 years old. On the other hand, employees contribute 20% of their wages.

Both contributions are subjected to a salary ceiling of S\$4,500, resulting in maximum contributions of S\$652.50 and S\$900 for each salaried person from the employer and employee respectively. This rate is also gradually reduced to 5% once the employee has passed 65 years old. This new policy attempts to increase the employability of older low-wage workers.

The government has also introduced measures to increase the take-home pay of low-wage workers by lowering the CPF contribution rates for this group. The revised CPF rates are posted on the CPF website (www.cpf.gov.sg).

Companies should learn about the CPF requirements prior to their initial manpower and financial planning as CPF contributions affects an employee's proposed wages. For example, an employee earning S\$5,000 per month will have to contribute S\$900 to his CPF account each month, reducing his take home pay to S\$4,100. Furthermore, his employer will have to contribute an additional \$652.50 into his CPF account. Thus, the employer is effectively paying S\$5,652.50 per month to hire this employee.

Employment Pass

Foreign professionals have to obtain an employment pass before they can take up employment or carry out any business in Singapore. Foreigners who intend to become business owners may apply for an "Approval-In-Principle Employment Pass" from the immigration authorities before registering their business or company with ACRA. The actual employment pass will be issued only when the foreigner is successful with the registration.

There are generally 3 types of employment passes:

P employment pass – for foreigners with acceptable tertiary / professional qualifications who are entrepreneurs or investors or who are seeking professional or executive positions. Applicant's basic salary should be more than S\$3,500 per month.

Q employment pass – for skilled workers and technicians with a basic monthly salary exceeding S\$2,500.

S employment pass – for foreign mid-level skilled professionals, specialists or technicians with educational qualifications of degree or diploma and a fixed monthly salary of at least S\$1,800. The number of S pass holders within a company is capped at 25% of the company's total workforce.

A new Personalised Employment Pass (PEP) is also available for foreign professionals who satisfy the criteria to offer them greater job flexibility.

This pass is not tied to a specific employer and pass holder is able to switch jobs within the country without the need to cancel and re-apply for another employment pass. The pass also enables the holder to remain in Singapore for up to six months in between jobs to evaluate new employment opportunities.

Please refer to the Ministry of Manpower's website (www.mom.gov.sg) for more details.